FBI Laboratory
Practices for the Calibration and Maintenance of Equipment

1 Purpose

These practices establish requirements for calibration, performance checks, and maintenance of equipment to ensure the accuracy and reliability of testing results. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

2 Scope

These practices apply to FBI Laboratory personnel who use equipment that has an effect on the validity of examinations and DNA databasing and to those personnel who coordinate maintenance and calibration services. This includes equipment outside the permanent control of the FBI Laboratory which is used for testing activities.

3 Practices

All equipment having an effect on the accuracy or validity of examination and DNA database results will be properly maintained and calibrated. Units, disciplines, and/or categories of testing ensure the equipment used for measurement is capable of achieving the measurement accuracy and/or measurement uncertainty and/or traceability required to provide a valid result.

3.1 Equipment and its software used for examinations or DNA databasing must meet the requirements of the relevant technical procedure or applicable specifications. Before being placed into or returned into service, and when necessary, equipment (including that used for sampling) that has a direct effect on the quality of an examination or DNA databasing is calibrated and/or checked by the unit, discipline, and/or category of testing to verify it meets the specifications. Additionally, maintenance may be performed on equipment to ensure it meets the applicable specifications or requirements.

3.2 Units, disciplines, and/or categories of testing will have procedures for handling, transport, storage, use, and planned maintenance of equipment in order to ensure proper functioning, or to prevent contamination or deterioration.

3.3 Units, disciplines, and/or categories of testing will take practicable measures to prevent unintended adjustments of equipment from invalidating test results.

3.4 Any equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements will be taken out of service. The equipment will be isolated to prevent use or clearly labeled or marked

as being out of service until it has been verified to perform correctly. Units, disciplines, and/or categories of testing will determine the effect of the defect or departure from specified requirements and implement nonconforming work procedures as specified in the Laboratory Operations Manual (LOM) - Practices for Addressing a Nonconformity when necessary.

3.4.1 If an instrument can be affected by a power interruption, units, disciplines, and/or categories of testing will check the instrument operation after a shutdown, whether deliberate or otherwise.

3.5 Resource Manager in Forensic Advantage

3.5.1 All equipment having a direct effect on the quality of an examination or DNA databasing or are part of an internal audit will be identified in Resource Manager in Forensic Advantage (FA) (with the exception of DNA equipment that is tracked in Sample Tracking and Control Software (STACS)). When a unit needs a new piece of equipment added to Resource Manager, they will contact the Research and Support Unit Instrument Operations and Systems Support (RSU IOSS) or the Scientific and Biometrics Analysis Unit Instrument Operations Group (SBAU IOG), as appropriate.

3.5.1.1 Each piece of equipment in Resource Manager will receive a unique identifier and barcode that will be placed on the equipment, when practicable.

3.5.1.2 When the equipment is entered into FA, under Resource Instance Details, the following information will be populated by RSU IOSS or SBAU IOG. Only RSU IOSS or SBAU IOG will update these fields.

- "Identifier" - Type or name of equipment
- "Asset ID" - Equipment serial number or other unique identifier
- "Entered in FA" - Date equipment added to FA
- "Owner" - Unit managing the equipment
- "Model Number" - Model number, if available
- "Manufacturer" - Vendor, if available
- "Description" - Standard RSU IOSS or SBAU IOG description for the equipment
- "Comments" - Property (F) number, if available

3.5.1.3 Each Unit Chief will ensure the equipment used in examinations and DNA databasing that requires calibration is identified in Resource Manager or STACS, as appropriate. Additionally, each Unit Chief will ensure the appropriate fields in Resource Manager are complete and current.

3.5.1.3.1 Units will update equipment calibration in Resource Manager or STACS, as appropriate, in a timely manner after calibration. Units will maintain calibration records including any calibration certificates. Software and firmware version records will be maintained by the units. Resource Manager is not used to track maintenance; therefore, units must track maintenance via another mechanism.

3.6 Calibration

3.6.1 Measuring equipment is calibrated when:

- the measurement accuracy or measurement uncertainty affects the validity of the examination or DNA databasing results, and/or
- calibration is required to establish metrological traceability of the examination or DNA databasing results.

3.6.2 Units, disciplines, and/or categories of testing will have a calibration program which they review and adjust as necessary in order to maintain confidence in the status of the calibration(s).

3.6.2.1 The program for the calibration of equipment will include:

a) a list of the equipment requiring calibration;
b) specifications for the calibration laboratory;
c) specified requirements for the calibration; and
d) the interval of calibration.

3.6.3 FBI Laboratory equipment requiring calibration will be labeled, coded, or otherwise identified to allow the user of the equipment to readily identify the calibration status or period of validity.

3.6.4 Equipment that requires calibration will not be used for examinations or DNA databasing if satisfactory calibration cannot be achieved. If the calibration has expired, personnel will verify the calibration status is satisfactory prior to using the equipment.

3.6.5 Calibration of Measuring Equipment, Reference Standards, and Certified Reference Materials

3.6.5.1 If available, suppliers of external calibration services for measuring equipment and/or certified reference materials used to establish or maintain metrological traceability will be one of the following:

a) a National Metrology Institute that is a signatory to the International Bureau of Weights and Measures (BIPM) International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA) with the calibration of measuring equipment and/or reference standard to be purchased or the certified reference material listed to be purchased in Appendix C of the BIPM key comparison database (KCDB); or
b) a service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) MRA, with the calibration of measuring equipment to be purchased listed in a scope of accreditation; or
c) an accredited reference material producer that is accredited to ISO 17034 by

an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC MRA, with a scope of accreditation covering the certified reference material to be purchased.

3.6.5.2 In situations where a supplier that meets 3.6.5.1 is not available, the competence, capability, and metrological traceability for the supplier and the external product or service being purchased will be confirmed by the unit(s), discipline(s), and/or category(ies) of testing using that supplier. Objective evidence of the confirmation will be maintained by the relevant unit(s), discipline(s), and/or category(ies) of testing.

3.6.5.3 If a certified reference material is changed in a way that alters the traceable measurement value, then the equipment used to alter the certified reference material will be evaluated by the unit(s), discipline(s), and/or category(ies) of testing using that equipment for applicability of measurement traceability accreditation requirements.

3.6.6 Units, disciplines, and/or categories of testing will ensure measurement results are traceable to the International System of Units (SI) through:

a) calibration provided by a competent laboratory; or
b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or
c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

3.6.7 When metrological traceability of measurements to SI units is not technically possible, units, disciplines, and/or categories of testing will demonstrate metrological traceability to an appropriate reference, for example:

a) Certified values of certified reference materials provided by a competent producer;
b) Results of reference measurement procedures, specified methods, or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

3.6.8 When calibration and reference material data will include reference values or correction factors, the units, disciplines, and/or categories of testing will have measures to ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

3.6.9 Unit Chiefs will ensure the calibration was completed and Resource Manager or STACS is updated to record the calibration information.

3.6.9.1 Unit Chiefs will ensure calibration certificates provided by a vendor are reviewed for accuracy and checked for conformance with applicable requirements for their needs. A record of this review will be maintained.

3.6.10 Calibration Interval

Unit Chiefs will ensure that equipment requiring calibration is calibrated within the required intervals as specified in level 2 documents. Manufacturers' operating guidelines should be consulted to determine the recommended calibration interval, if applicable. However, equipment used infrequently, such that recommendations by the manufacturer cannot be followed, will be calibrated or have its calibration status verified prior to use.

New equipment or equipment that has undergone repair or maintenance that affects calibration, will have its calibration status verified before being used in examinations or DNA databasing.

3.6.10.1 Intermediate Checks

When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks will be carried out according to an applicable procedure(s).

3.6.11 Calibration Records

3.6.11.1 Calibration records, including calibration certificates, for all equipment will be maintained by the units.

3.6.11.2 Resource Manager fields will be used to record the following information for balances, calipers, micrometers, pipettes, and class 1 weights, except for DNA equipment tracked in STACS.

When a Resource Action (calibration) is entered, the following fields in Resource Manager will be populated by the unit:

- "Performance Action" - Calibration option
- "Date of Action / Time of Action" - Date and time (separate fields) when calibration conducted
- "Performed By" - Person performing/recording the maintenance
- "Comments" - Additional information about the calibration conducted

When the equipment is calibrated, the following field in "Resource Instance Details" must be updated by the unit:

- "Expiration Date" - Expiration date for the current calibration

3.6.11.3 If calibrations performed by an outside vendor are coordinated by the Forensic Analysis Support Unit (FASU) or SBAU IOG (e.g., balance calibrations), FASU or SBAU IOG will provide the units with copies of calibration records (physical or electronic) provided by the vendor. Refer to section 3.6.9.1 for additional requirements.

3.7 Performance Checks

In instances where calibration is not required or appropriate, performance checks should be carried out at appropriate intervals to verify that the equipment is functioning properly. Performance check procedures will be included in the appropriate technical procedure in which the equipment is used, in a stand-alone maintenance document, or in manufacturer-supplied procedures for maintenance. These procedures will reflect current performance requirements based on the use of the equipment and will be readily available to appropriate personnel.

3.7.1 Performance Check Records

Performance check records will be maintained. If a bound notebook is used to capture the performance check records, only the cover or first page of the notebook must be labeled with the equipment's unique identifier. Performance check records may also be maintained in case notes. These records will include, at a minimum:

- Type or name of equipment.
- Equipment serial number or other unique identifier.
- Date of the performance check.
- Results of the performance check.
- Material used for the performance check, including unique identifying information, if applicable.
- Acceptance criteria, if applicable.
- Identity of person performing the performance check.

3.8 Maintenance

3.8.1 Units, disciplines, and/or categories of testing will have maintenance procedures for equipment that has a direct effect on the quality of an examination or DNA databasing.

3.8.2 Maintenance Intervals

Maintenance can be performed on equipment:

- according to a regular, predetermined schedule (e.g., microscope maintenance performed annually);
- based on routine monitoring of performance;
- following adjustment of common parameters (e.g., head pressure, solvent degas).

Maintenance is performed on equipment in order to ensure reproducible and uninterrupted operation; maintenance may also be corrective. Maintenance performed on a regular, predetermined schedule is based on manufacturer's recommendations (as available and relevant), historical observations of issues, operating experience, and/or how often the equipment is used. The interval for any equipment requiring preventive maintenance will be specified in a level 2 document.

3.8.3 Corrective maintenance occurs when a piece of equipment cannot be properly calibrated, fails an intermediate check, fails to meet the performance characteristics established for the procedure(s), or produces unacceptable results. The equipment will be taken out of service until corrective maintenance is completed.

3.8.4 Maintenance Records

3.8.4.1 Maintenance records will be maintained by the units. If a bound notebook is used to capture maintenance records, only the cover or first page of the notebook needs to be labeled with the equipment's unique identifier.

3.8.4.2 If maintenance performed by an outside vendor is coordinated by FASU or SBAU IOG (i.e., microscope maintenance), FASU or SBAU IOG will provide the units with the original maintenance records (physical or electronic) provided by the vendor. Unit Chiefs will ensure maintenance records provided by a vendor are reviewed for accuracy and checked for conformance with applicable requirements for the unit's needs. A record of this review will be maintained.

3.9 Refrigerator and Freezer Monitoring

All refrigerators and freezers that store evidence and/or items that have a direct effect on the validity of examinations or DNA databasing have their temperatures monitored and maintained as needed.

4 Records

The following records will be maintained through one accreditation cycle:

- Entries in Resource Manager or STACS for all equipment having a direct effect on the quality of an examination or DNA databasing or part of an internal audit.
- Calibration records, including a review of vendor provided certificates, will be maintained by the units with specified calibration fields maintained in Resource Manager.
- Maintenance records, including a review of vendor provided records, will be maintained by the units.
- Performance check records will be maintained by the units.

5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Operations Manual, Federal Bureau of Investigation, Laboratory Division, latest

revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
10	06/03/19	Entire document revised to conform to new accreditation requirements. Broadened scope in section 2 to include personnel who coordinate services, and equipment outside the FBI Laboratory's permanent control. Updated unit names following Laboratory realignment. Updated list of references in section 5.
11	12/21/20	Minor typos corrected and edits made throughout document for clarity. 3 – added traceability 3.5.1 and 3.5.1.2 - added SBAU IOG 3.6.5.1-removed reference standards 3.6.9.1 - added to cover UCs ensuring review of calibration certificates and recording that review 3.6.10.1 - changed performance to calibration status 3.8.2 - clarified intervals for preventive maintenance specified in level 2 documents 3.8.3 - clarified taken out of service until corrective maintenance is completed 3.8.4.2 - added to cover UCs ensuring review of maintenance records and recording that review for equipment maintenance coordinated FASU or SBAU IOG 4 – updated records to include reviews of calibration certificates and maintenance records and added LOM

Approval

Redacted - Signatures on File

Laboratory Director Date: 12/18/2020

Quality Manager Date: 12/18/2020